DETAILED ACTION

Status of the Application

Claims 1 and new claims 37-59 are pending. Applicant's amendments and addition of new claims necessitates a new restriction requirement below. Altogether, the claims as now amended require the Examiner to search and examine a multitude of molecules having a variety of different combinations of modifications in the sense strand, the antisense strand, or both. Numerous combinations and configurations of chemically modified nucleic acid molecules are specifically claimed, imposing a serious burden on the examiner.

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1 and 36-53, drawn to chemically modified nucleic acid molecule wherein the antisense strand is complementary to SE ID No. 709 and further comprising a sense strand and a separate antisense strand wherein each strand is 18 to 27 nucleotides and wherein about 50 to about 100 percent of the nucleotides in the sense and antisense strand are chemically modified and one or more purine nucleotides are 2'-O-methyl and one or more pyrimidine nucleotides are 2'-deoxy-2'-fluoro nucleotides, classifiable in class 536, subclass 24.5.

II. Claims 54-55, drawn to chemically modified nucleic acid molecule comprising a sense strand an a separate antisense strand wherein each strand is 18 to 27 nucleotides and wherein the sense strand includes a

terminal cap moiety at the 5' end, 3' end or both ends of the sense strands, one or more of the nucleotides in the sense and antisense strand are 2'-O-methyl and one to ten of the pyrimidine nucleotides present in the sense and antisense strand are 2'-deoxy-2'fluoro nucleotides, classifiable in class 536, subclass 24.5

III. Claims 56-57, drawn to chemically modified nucleic acid molecule comprising a sense strand an a separate antisense strand wherein each strand is 18 to 27 nucleotides and wherein at least 35% of the nucleotides of each strand comprises a modification selected from the group as listed and at least one sugar modification is a 2'-O-methyl and at least two of said modifications are different from each other, classifiable in class 536, subclass 24.5.

The inventions are distinct, each from the other because of the following reasons:

Inventions I, II and III are directed to related chemically modified nucleic acid molecules comprising a sense and an antisense strand wherein the antisense strand comprises 18 to 27 of the BACE RNA nucleotide sequence. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the chemically modified nucleic acid molecules are mutually exclusive because each nucleic acid

molecule is structurally distinct. For example, group I is drawn to a chemically modified nucleic acid molecule wherein up to 100 percent of the sense or antisense strands comprise a modified group selected from 2;-O-methyl, 2'-deoxy-2'-fluoro, 2'-deoxy, phosphorothioate or deoxyabasic which is a structurally distinct molecule than claimed in group II wherein only one of the nucleotides in each strand or one purine or pyrimidine in each strand are chemically modified. Further group III is drawn to a chemically modified nucleic acid molecule wherein at least 35% of the sense or antisense strands comprise a modified group selected from 2;-O-methyl, 2'-deoxy-2'-fluoro, 2'-deoxy, phosphorothioate or deoxyabasic which is a structurally distinct molecule than group I or group II. Moreover, the chemically modified nucleic acid molecules of groups I, II and III are not disclosed as capable of use together. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Newly submitted claims 58-59 are withdrawn as being drawn to non-elected invention because it is directed to an invention that is independent or distinct from the elected invention for the following reasons: the composition comprising a chemically modified nucleic acid of the instant claims and the method of new claims 58-59 are drawn to inhibiting expression of human BACE gene using said composition in claim 1 are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as

claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the process can be practiced using a material different product, such as a single stranded nucleic acid molecule. Furthermore restriction is proper because the subject matter is divergent and non-coextensive and a search for one would not necessarily reveal art against the other. It is therefore a burden to search these inventions in a single application.

Since applicant has received an action on the merits for the originally presented invention, this invention has been constructively elected by original presentation for prosecution on the merits. Accordingly, claims 58-59 are withdrawn from consideration as being directed to a non-elected invention. See 37 CFR 1.142(b) and MPEP § 821.03.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and the product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise require all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103 and 112. Until all claims to the elected product

are found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowable product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder**. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Restriction for examination purposes as indicated is proper because all these inventions listed in this action are independent or distinct for the reasons given above and there would be a serious search and examination burden if restriction were not required because one or more of the following reasons apply:

(a) the inventions have acquired a separate status in the art in view of their different classification;

(b) the inventions have acquired a separate status in the art due to their recognized divergent subject matter;

(c) the inventions require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries);

(d) the prior art applicable to one invention would not likely be applicable to another invention;

(e) the inventions are likely to raise different non-prior art issues under 35 U.S.C. 101 and/or 35 U.S.C. 112, first paragraph.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a invention to be examined even though the requirement may be traversed (37 CFR 1.143) **and (ii) identification of the claims encompassing the elected invention**.

The election of an invention may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse. Traversal must be presented at the time of election in order to be considered timely. Failure to timely traverse the requirement will result in the loss of right to petition under 37 CFR 1.144. If claims are added after the election, applicant must indicate which of these claims are readable on the elected invention.

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Should applicant traverse on the ground that the inventions are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable

over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly Chong whose telephone number is 571-272-3111. The examiner can normally be reached Monday thru Friday between 7-4 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Schultz can be reached at 571-272-0763. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Kimberly Chong/
Examiner AU 1635